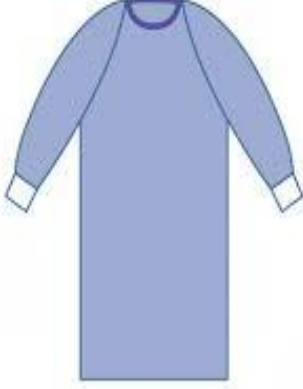
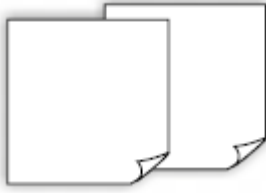
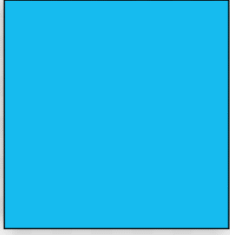




MHKMEDİKAL
TEKSTİL

DATASHEET

Standard Surgical Gown					
Drawing	Item	Size	Material	Detail	Piece
	Standard Surgical Gown	L Lenght 150 cm	SMS 40 - 43gsm	Full Ultrasonic Raglan Sleeves	1
	Towels	30 x 40 cm			2
	Wrapping	50 x 50 cm	SMS		1

- **REF: 233401**
- **Material of Gown: SMS**
- **Weight of Gown Fabric: 40-43 gr/m²**
- Antiallergenic
- Air Permeable
- Non-Linting
- Straight sleeves
- Belt with indication label



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- Knitted cuffs
- Neck fastening with velcro
- Impervious Medical Fabric
- Puncture resistant
- **Sterilization Type:** EO Sterile
- **Shelf Life:** 5 years
- **Colour:** Blue
- **Packing:** Pouch (PE/Paper), Peel to Open
- Class Is Sterile accordingly to the Directive 93/42
- Latex free

 **MHK MEDİKAL TEKSTİL
SAN. VE TİC. LTD. ŞTİ.**
Körkün Mahallesi Hidayet Cad. No:23/1 Oğuzeli
Tif. 0342 341 93 66 Faks: 0342 341 93 67 GAZİANTEP
Tic.Sicil No: 40345 SUBURCU V.D. 020 005 1520



EU DECLARATION OF CONFORMITY



Manufacturer Name	: MHK MEDİKAL TEKSTİL SAN. TIC. LTD. STİ
Adress	: Körkün Mahallesi Hidayet Caddesi No 23 Oğuzeli /Gaziantep / TURKEY
Product Trade Name	: Disposable Sterile Drapes, Gowns And Procedure Packs (Trays) (See Annex List of the Product)
Directive	: Regulation (EU) 2017/745 on Medical Device Regulation
Brand	: MHK
Basic UDI-DI	: 0868082921DRPGWNFX
Classification	: According To Annex VIII Of Regulation (Eu) 2017/745 (Medical Device Regulation (MDR)) Non-Invasive, Non-Active Medical Device, Class I Sterile, Rule 1
Conformity Assesment	: According to Regulation (EU) 2017/745 on medical devices Annex – XI Part A PRODUCT CONFORMITY VERIFICATION

We herewith declare that:

Those above products with CE marking which are manufactured by our company all comply with REGULATION (EU) 2017/745 ON MEDICAL DEVICES, and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

STANDARTS APPLIED :

EN ISO 13485	EN ISO 11135	EN ISO 13795-1
EN ISO 15223-1	EN ISO 14698-1	EN ISO 10993-1
EN ISO 14971:2019	EN ISO 14698-2	EN ISO 10993-5
EN ISO 10993-10	ISO 11737-1	

A statement that the declaration of conformity is issued under the responsibility of the manufacturer.

Place/Date : GAZİANTEP / 27.02.2023
Authorized Person : MURAT KEKEÇ
Title : General Manager

Signature, Stamp



ANNEX I: LIST OF THE PRODUCTS:

Document ID: TD-09 / 10

PRODUCT NAME	RISK CLASS	EMDN CODE	REF CODE	UDI-DI
STANDARD SURGICAL GOWN	Class Is	T020401	16-041-03-K	8680829210136

Document ID: TD-09 / 10



C E R T I F I C A T E

Production Quality Assurance Medical Devices Directive 93/42/EEC Annex V

Company Name : Mhk Medikal Tekstil Sanayi ve Ticaret Limited Şirketi

Company Address : Körkün Mah. Hidayet Cad. No:23/1 Oğuzeli GAZİANTEP / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex V

Product : Sterile Disposable Surgical Drape, Gown and Sets - Class Is

GMDN : 35778, 47783

Certificate Number : M.2014.106.3565

Report Number : MD.2292.YB

Initial Assessment Date : 12.03.2014

Registration Date : 01.10.2014

Recertification Assessment Date : 26.08.2019

Reissue Date / No : 13.12.2019/01

Revision Date /No : -

Expiry Date : 27.05.2024



UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.



UDEM hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex V, section 4 of the aforementioned directive. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev.ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

akssert

CERTIFICATE

MHK Medikal Tekstil
Sanayi ve Ticaret Limited Şirketi

Körkün Mah. Hidayet Cad. No:23 Oğuzeli GAZIANTEP / TURKEY

ISO 9001:2015

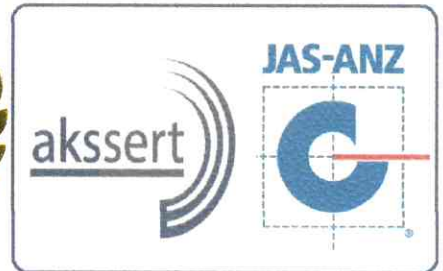
Scope: Sterile and non-sterile disposable surgical gowns, patient gowns, patient clothes, surgical drapes and surgical drapes and gowns packages and personal protective overalls and aprons manufacture, sale and export, sterile and non-sterile surgical gloves, examination gloves, PE gloves, masks, bonnets, booties, setting drip sets, infusion sets imports and exports

EA Code: 4-14-23-29

Hereby, AKSSERT Audit and Certification Ltd. Co., certifies that the above stated company gave the appropriate management system according to the requirements of the above standard. This certificate valid for 3 years since the decision date as long as the system is effectively maintained and surveillance audits are carried out. The validity of certificate can be checked through www.akssert.com, www.jas-anz.org/register. The Certificate is property of AKSSERT Audit and Certification Ltd. Co. and shall be returned if requested.



AKSSERT Audit and
Certification Ltd. Co.



Certificate Number : 52233

Registration Date : 09.04.2021

Reissue Date : 23.03.2022

Expiry Date : 08.04.2023

Address: Mutlukent Mah. 1920. Cadde No:28 Çankaya / ANKARA - TURKEY

Phone: +90 312 284 99 44 (pbx)

E-mail: info@akssert.com Web: www.akssert.com

akssert

CERTIFICATE

MHK Medikal Tekstil
Sanayi ve Ticaret Limited Şirketi

Körkün Mah. Hidayet Cad. No:23/1 Oğuzeli GAZIANTEP / TURKEY

ISO 13485:2016

Scope: Manufacturing, sales and export of sterile and non-sterile disposable surgical gown, patient gown, patient wearings, aprons and surgical sets, purchasing, sales, export and import of sterile and non-sterile surgical glove, examination glove, pe glove, masks, bonnets, galosh, bistoury, drop set, serum sets, wooden tongue spatula

Hereby, AKSSERT Audit and Certification Ltd. Co., certifies that the above stated company gave the appropriate management system according to the requirements of the above standard. This certificate valid for 3 years since the decision date as long as the system is effectively maintained and surveillance audits are carried out. The validity of certificate can be checked through www.akssert.com, www.jas-anz.org/register. The Certificate is property of AKSSERT Audit and Certification Ltd. Co. and shall be returned if requested.

The reference standard is ISO 13485:2016

AKSSERT Audit and
Certification Ltd. Co.



Certificate Number : 85091
Registration Date : 04.09.2013
Previous Certification Cycle Expiry Date: 03.09.2022
Recertification Audit Date: 15.03.2022

Reissue Date : 22.08.2022
Revision Date/No : -
Expiry Date : 03.09.2025

Address: Mutlukent Mahallesi 1920. Cadde No:28 Çankaya/ANKARA - TÜRKİYE
Phone: +90 312 284 99 44(pbx)

E-mail: info@akssert.com Web: www.akssert.com